COVIDIEN

Operating Manual

Genius™ 3

Tympanic Thermometer and Base

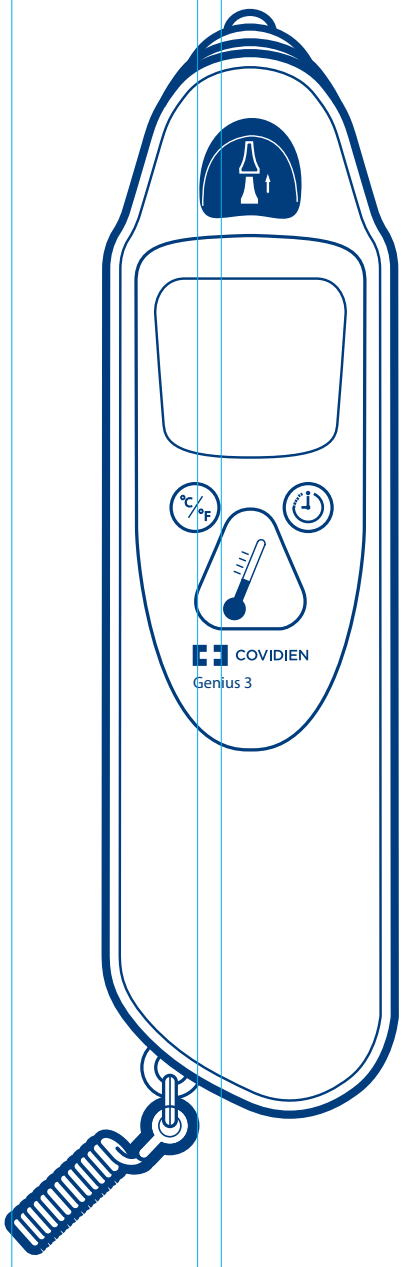


Table of Contents

Section I — Thermometer Overview

The Genius™ 3 Tympanic Thermometer is an ADJUSTED MODE ear thermometer that provides fast and accurate measurements of patient temperatures. The Genius 3 Tympanic Thermometer is an ear canal thermometer with measurement site adjusted modes, which include oral and rectal temperatures. The site modes are explained further in Section IV, Instructions for Use.

This operator's manual was prepared for the operator, lay operator and lay responsible organization to use the Genius™ 3 Tympanic Thermometer and Base. This manual contains instructions for use, precautions, and available maintenance and service information. For accurate results, the operator must read this manual thoroughly before attempting to use the thermometer.

Initial Set Up

- Unpack the thermometer and check it for damage.
- If using the wall or cart mount (sold separately) for the base unit, refer to the installation sheet.
- When first used, the thermometer will show the default settings: ear mode (EAR) and the Celsius scale (°C).
- If the thermometer has been stored outside of the listed ambient temperature range (see section X), allow thermometer to acclimate to the room temperature for a minimum of 30 minutes prior to use.

Features

- Temperature measurement meets ISO standards – See Section X
- Peak Select System – See Section IV Instructions for Use
- Temperature measurement range of 33.0°C to 42.0°C (91.4°F to 107.6°F)
- After a temperature has been acquired, the °C/°F button changes between °C and °F
- Audible and visual indication of completed temperature measurement
- Disposable single use probe covers designed to aid in the prevention of cross contamination
- Low and dead battery indicators
- "Sleep" mode stores the last temperature and saves battery life
- 15, 30, 45, and 60 second pulse timer functions
- The thermometer housing can be wiped clean with common cleaning agents – See Section VI, Cleaning for instructions
- Base unit protects the thermometer tip and stores probe covers for easy access
- Easy to read LCD display with icons
- Unit is designed for right and left hand use
- Provides temperature measurement in 1 - 2 seconds

Section II — Safety and Warnings

Note to healthcare personnel who provide training to lay operators or lay responsible organizations:

Be sure to include all of the Dangers, Warnings and Cautions below when providing training to Lay Operators, especially for home care use. Lay Operators should be instructed to contact Customer Service if there is a change in the performance of the thermometer. Additionally, Lay Operators should be instructed on proper cleaning procedures to avoid hazards such as cracks or water ingress. Lay Operators should also be trained on proper use (e.g. out of range ambient temperatures) of the thermometer. For guidance on training, please contact Customer Service.

Indications for Use:

The Genius 3 Tympanic Thermometer is intended for use in patients in acute and alternative care settings to provide temperature measurements from the tympanic membrane and equivalent measurements of oral and rectal temperature based on the tympanic reading.

Danger:

- Thermometer cable could lead to strangulation.
- Swallowing of Probe Cover could lead to serious medical injury.
- Used probe covers must be treated as infectious biological waste. They must be disposed of in accordance with current medical practices and local regulations.

Warning:

- Avoid using oral offset for patients younger than 5 years old.
- Do NOT use the thermometer in Emergency Medical Services Environment.
- Incorrect placement of thermometer in the ear canal could lead to permanent injury.
- Fluid ingress may reduce battery life and affect performance. Cleaning instructions should be followed. See Section VI to prevent fluid from entering the unit.
- Do NOT modify or change the equipment in any way.
- Do NOT use any other probe covers with the thermometer. Other probe covers will cause inaccurate readings.
- Do NOT use the thermometer on patients with ear drainage, blood, brain or spinal fluid, vernix, ear wax plugs, or foreign bodies in the ear canal.
- Ensure that the probe tip seals the ear canal prior to taking a temperature. Failing to seal the ear canal will result in a loss of accuracy.
- The thermometer is intended to be used in the electromagnetic environment specified in section XIII-Electromagnetic Conformity Declaration of this operating manual. Use of the thermometer in electromagnetic environments outside of the specified environments can cause erroneous temperature readings. Refer to pages 14 through 17 for additional information.
- Do NOT use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, nitrous oxide, or in an oxygen rich environment.
- Pressure equalization (PE) or tympanostomy tubes will not adversely affect accuracy. For patient comfort, wait one week after surgery before using the thermometer and Base.
- Excessive eardrum scarring may cause low temperature readings.
- Do NOT use lithium batteries. Do NOT mix alkaline and lithium/rechargeable batteries.
- Alkaline batteries must be disposed of in accordance with local policy.
- Expired or old equipment must be disposed of in accordance with institutional policy.

Caution:

- Read this manual carefully before using the device.
- Once the cover is on the thermometer, do not point the probe tip at any heat generating object, including hands, computers, windows as this will cause an inaccurate temperature reading.
- U.S. federal law restricts the sale of this device to physicians.
- Keep away from reach of children, pets, and pests when used in a home environment.
- Always place the thermometer in the base after use.
- For any damage to the unit, especially the probe tip, contact customer service.
- The thermometer is a precision optical instrument. Handle the device carefully and do not drop.
- Before use, ensure that the probe tip is clean and clear of any debris. If the thermometer tip becomes soiled, gently clean with a lens wipe or lint free swab. The tip should appear shiny and free of fingerprints and/or debris. For full cleaning directions see Section VI: Cleaning & Disinfecting.
- Always install a new probe cover prior to taking a temperature. The probe cover film should be smooth with no holes, tears, or wrinkles.
- Use of the thermometer without a probe cover will cause inaccurate readings.
- Patients with removable hearing aids should remove them at least 10 minutes before to taking a temperature. Implanted devices generally do not affect ear temperature.
- When checking patient temperature during cold weather conditions, allow the patient to adjust to room temperature before use.
- If the thermometer has been stored outside of the listed ambient temperature range (see section X), allow thermometer to acclimate to the room temperature for a minimum of 30 minutes prior to use.
- Under normal conditions, earwax does not affect accuracy. However, earwax plugs can cause a low reading.
- Wait at least two minutes before taking another reading in the same ear.
- Remove the batteries if the unit will not be used for a long period of time.
- This thermometer system was designed to meet IEC 60601-1 safety standards. For clarification purposes, the thermometer with installed probe cover is considered an Applied Part and has been tested and evaluated accordingly.

Section III — Icon Identification


Eject Button

°C/°F Button


Timer Button


Scan Button

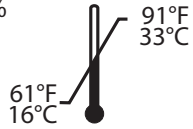

Choking Hazard

Non-Sterile

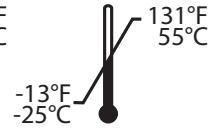
For prescription use only

Storage and transportation humidity limitation

Operating Humidity limitation



Operating temperature range



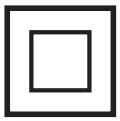
Storage and transportation temperature range


Keep away from sunlight


Keep dry


Caution, for indoor use only


Type BF protection (degree of protection against electrical shock - there is no conductive connection to patient.


Class II equipment


Non-ionizing electromagnetic radiation

Authorized representative in the European community

Catalog number


Identification of a substance that is not contained or present within the product or packaging.

DEHP
Not made with DEHP

Not made with natural rubber latex


Do not use if package is opened or damaged.

CE mark


Dispose of as electrical or electronic waste


Follow instructions for use

MR Unsafe (magnetic resonance)


Manufacturer


Date of manufacture

Serial number

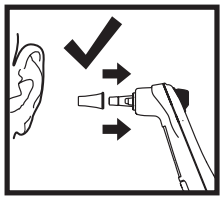
Batch code

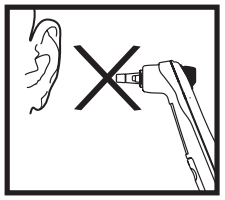
Protection against fluid ingress: Drip proof

ETL Classified

5009653

Medical Electrical Equipment, Devices, and Device Software


Probe cover installed


Probe cover not installed

Medical Electrical Equipment

Genius 3 Tympanic Thermometer and Base

(1) Classified with respect to electrical shock, fire and mechanical hazards in accordance with IEC 60601-1:2005/AMD1:2012; AAMI/ANSI ES60601-1:2005(R)2012+A1:2012; EN 60601-1:2006/A1:2013

(2) Classified with respect to electrical shock, fire, mechanical and other specified hazards in accordance with CAN/CSA C22.2 No. 60601-1:14

Section IV — Instructions for Use

Peak Select System

The Genius 3 Tympanic Thermometer and Base uses the patented Peak Select System. It takes multiple readings and selects the highest temperature for display.

Equivalence Modes

Genius 3 Tympanic Thermometer and Base is an ear canal thermometer for infants, children, and adults.

Prior to the introduction of tympanic thermometry, patient temperatures were measured in the mouth (oral), or in the rectum (rectal). If a patient's temperature was measured at the same time with each of these methods, different temperatures would result. The Genius 3 Tympanic Thermometer and Base accounts for the average difference at each of these sites by adjusting the displayed temperature.

The following equivalence modes are available on the Genius 3 Tympanic Thermometer and Base. Data is available from Covidien on request.

Ear: In ear (EAR) mode, the display will indicate the absolute temperature without adjustment. The EAR mode is also the UNADJUSTED MODE or DIRECT MODE of temperature acquisition.

Oral: In oral (ORL) mode, the ear temperature is adjusted to display the oral temperature equivalent.

Oral Mode = Ear Mode -0.09 °C
Clinical Bias = 0.09 °C
Limits of Agreement = (+/-) 0.64 °C
Clinical Repeatability = 0.13 °C
Reference Body Site = Oral Cavity
Measuring Body Site = EAR

Rectal: In rectal (REC) mode, the ear temperature is adjusted to display the rectal temperature equivalent.

Rectal Mode = Ear Mode +0.56 °C
Clinical Bias: = 0.5 °C
Limits of Agreement: = -0.47 / +1.66 °C
Clinical Repeatability: = 0.231 °C
Reference Body Site: = Rectum
Measuring Body Site: = EAR

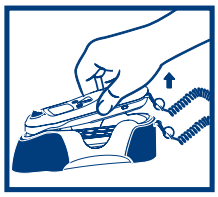
Probe Covers

The Genius 3 Tympanic Thermometer and Base uses single use probe covers. The use of non-Covidien probe covers will cause incorrect readings.

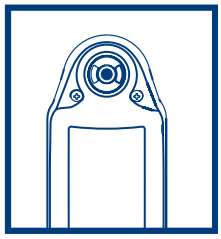
The probe covers are held in a cassette stored in the thermometer base. To load a probe cover on the thermometer, firmly push the probe tip into the probe cover. When installed on the thermometer, the probe cover film should be smooth with no holes, tears, or wrinkles. After the reading has been taken, eject the probe cover by pressing the eject button. Probe covers should be disposed of properly after use. In order to help prevent and control infection, always use a new probe cover before taking a reading.

Temperature Measurement

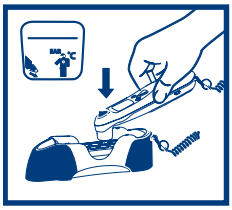
Training on the use of the Genius 3 Tympanic Thermometer and Base is important for user competence. Please follow these basic steps below and for further information please visit www.covidien.com



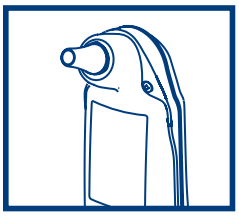
1. Visually inspect the patient's ear canal. Remove the thermometer from the base.



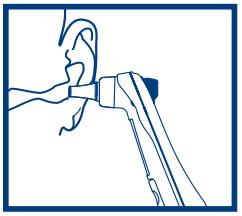
2. Inspect the probe lens. If any debris is present, clean the probe tip per the directions in Section VI, Cleaning. If the probe tip is clean, proceed to step 3.



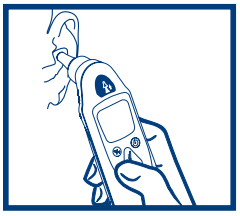
3. Press the scan button to verify functionality (all LCD segments displayed) and mode selection on the LCD screen. Install a probe cover by firmly pressing the probe tip into a probe cover. After the probe cover is installed, the thermometer will display dashes, the site mode, and the probe tip icon.



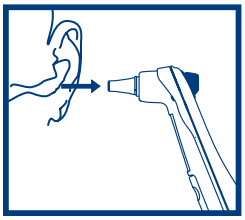
4. Inspect the probe cover to make sure it is fully seated with no spaces between the cover and the tip base. Also, make sure there are no holes, tears, or wrinkles in the plastic film.



5. Place the probe in the ear canal and seal the opening with the probe tip. For consistent results, ensure that the probe shaft is aligned with the ear canal.

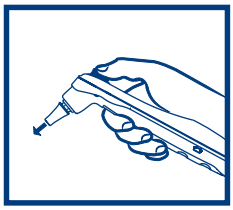


6. Once positioned lightly in the ear canal press and release the scan button. Wait for the triple beep before removing the thermometer.

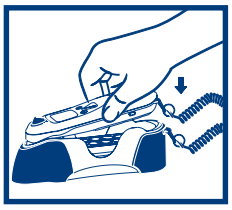


7. Remove the probe from the ear as soon as the triple beep is heard.

8. The patient temperature and the probe cover eject icons will be displayed. Note the "*" means non-ear mode.



9. Press the eject button to eject the probe cover into a proper waste container.



10. Return the unit to the base after use.

Temperature Recall

After a reading has been taken, the thermometer will enter "off" mode within about 10 seconds. The reading can be recalled with the scan button or by pressing and holding the °C/°F button.

Temperature Display - Toggle °C or °F

While a reading is shown on the display, press and hold the °C/°F button to change between Celsius and Fahrenheit.

Off Mode

The thermometer will go into off mode after 30-40 seconds of non-use. To wake up the thermometer, install a new probe cover. This off mode helps improve battery life.

Pulse Timer Mode

1. Press and hold the timer button to enter Timer mode. Press again to start the timer. The timer will run from 0 to 60 seconds.
2. The thermometer will beep once at 15 seconds, twice at 30 seconds, three times at 45 seconds, and four times at 60 seconds.
3. Pressing the timer button while the timer is displayed will return the thermometer to "off" mode.
4. At the end of the 60 seconds, the thermometer will wait two seconds and then enter sleep mode.
5. Return the thermometer to base for storage.

Thermometer Display Icons and Alarms

The thermometer communicates to the user using the LCD display and audible beeps. When a probe cover is installed or the batteries have been changed, the thermometer completes a system reset. The thermometer also performs a self-test to ensure that the device is working correctly.

Alarm Condition	Display Mode	
Patient temperature above specified range		
Patient temperature below specified range		
Ambient Temperature above specified range		
Ambient Temperature below specified range		
Low Battery		The LCD shows the low battery icon. The low battery icon will stay on until the batteries are changed or until the dead battery display appears. Once the low battery icon is shown, about 100 readings can be taken.
Dead Battery		The LCD shows the dead battery display. When any button is pressed this display will flash 3 times and then the LCD will turn OFF. Once the dead battery icon is shown, the batteries must be changed before the unit can be used.

If System Error "1" and System Error "2" are shown, the room conditions are too unstable for the device to be used. Allow the device to stabilize for 20 minutes before use.

If System Error 1 is shown, the thermometer has an internal memory checksum error (self-diagnostic test failure). Install a new probe cover to reset the unit. If the system error does not clear, contact the service center.

If System Error 2 is shown, the thermometer is out of calibration (e.g. a calibration variable is outside of the expected range). Contact the service center.

For any other System Error, install a probe cover to reset the unit. If the system error does not clear, contact the service center. Service addresses can be found in Section XI, Customer Service.

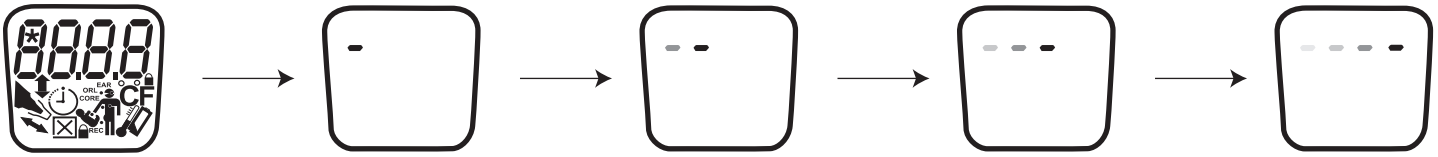
Biotech Mode

Biotech Mode contains the site mode options and can display the installed software version. All site mode settings in Biotech Mode are retained through power cycles, such as changing batteries.

The factory default settings are shown below:

Temperature mode	**°C (unlocked)**
Site mode	Ear
Site text	On

To enter Biotech Mode the thermometer must first be in "off" mode or sleep mode. While the thermometer is in "off" mode or sleep mode, press and hold the timer and °C/°F buttons for four seconds. All LCD segments will light for one second, the thermometer will beep once, and the display will show scrolling dashes. Press the timer button to cycle through the biotech modes. When options are available within a mode, the °C/°F button cycles through the options.



Pressing the timer button after the site text display will return the user to the installed software version.

The device will exit Biotech Mode after 30 seconds of non-use. To manually exit Biotech Mode press and hold the °C/°F and timer buttons for one second. Any changes are saved.

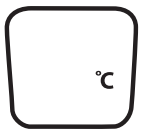
The biotech mode sequence is shown below:

Software version

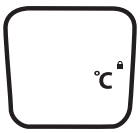
Displays the installed software version of device. Where "00" is the current software version.

Temperature mode

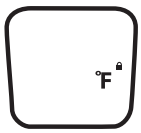
°C (unlocked)



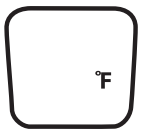
Locked °C



Locked °F



°F (unlocked)



Site mode

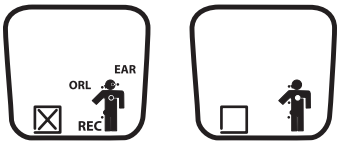
Ear

Oral

Rectal

Site text

Pressing the °C/°F button when in this mode turns the body site text labels on or off. The labels will remain on when an "X" appears inside the box icon, and the text will remain off when the box is empty.



Section V — Preventative Maintenance

A checker/calibrator is available for this device or the device can be sent in for service. The device must be checked for calibration every 25 weeks or whenever calibration is in question. If not able to calibrate, contact your Covidien representative for details. Harsh use or harsh environmental conditions may result in the need for more frequent checks. If the unit is dropped, abused, or stored at less than -25°C, or above 55°C, check it before the next use.

Section VI — Cleaning & Disinfecting

Cleaning

Genius 3 Thermometer Body, Base, and Coil Cord:

A mild, common dish washing liquid detergent, such as Dawn®, should be used for general cleaning of the thermometer body, base, and coil cord. This detergent should be used with a 20:1 ratio water to detergent mixture. The water and detergent mixture should not exceed 55°C (130°F).

Caution: The probe tip of the Genius 3 thermometer **should not** be cleaned with mild detergent.

Genius 3 Thermometer Probe Tip and Lens:

The probe tip and lens can be cleaned using a 70% Isopropyl alcohol wipe such as Webcol™*, Curity™*, or equivalent.

Caution: The use of other cleaners and disinfectants may cause significant damage to the Genius 3 thermometer and base and may void warranty. Never use an abrasive pad on any surface of the Genius 3 thermometer.

Cleaning frequency:

It is recommended that the Genius 3 thermometer, base, and coil cord be cleaned after each use.

Directions for Cleaning:

Genius 3 Thermometer Body, Base, and Coil Cord:

While cleaning the Genius 3 thermometer body, a probe cover should be installed on the thermometer. This will prevent damage to the probe tip and probe lens. Clean the surfaces of the thermometer body, base, and coil cord with a damp cloth using a mild detergent as previously described, removing all visible soil. Ensure all excess fluid is squeezed from the cloth before cleaning. If the cloth is excessively wet, the detergent and water solution may penetrate the thermometer and affect functionality. After cleaning the thermometer body, base, and coil cord wipe the thermometer with a clean lint free damp cloth to remove the mild detergent mixture. Dry the thermometer with a clean lint free cloth. Never use an abrasive pad or an abrasive cleaner on the Genius 3 thermometer, base, or coil cord.

Genius 3 Thermometer Probe Tip and Lens:

The thermometer probe tip and lens can be cleaned using a 70% isopropyl wipe such as Webcol™*, Curity™* or equivalent. Carefully remove all foreign matter from the thermometer probe tip and lens. After the foreign matter has been removed, dry the lens at the end of the thermometer probe tip with a lint free swab, cotton ball, or lens wipe. The thermometer lens must be free from fingerprints and / or smudges for proper operation. After cleaning the thermometer probe tip and lens, allow the thermometer to air dry completely.

Disinfection

Genius 3 Thermometer Body, Base, Coil Cord, Probe Tip and Lens:

The Genius 3 thermometer body, base, coil cord, probe tip, and lens can be disinfected by dampening their surfaces with 70% isopropyl alcohol.

Disinfection frequency:

It is necessary to disinfect the Genius 3 thermometer after each use.

Directions for Disinfecting the Thermometer Body, Base, Coil Cord, Probe Tip, and Lens:

Dampen the surfaces of the devices using isopropyl wipes such as Webcol™*, Curity™*, or an equivalent lint free wipe wetted with 70% isopropyl alcohol. Wipe the devices as necessary to maintain visual wetness for a minimum duration of 1 minute. Ensure that the thermometer lens is free from fingerprints and / or smudges for proper operation. After disinfecting the thermometer probe tip and lens, allow the thermometer to air dry completely.

Caution: The Genius 3 Tympanic Thermometer and Base is a non-sterile device. Do not use ethylene oxide gas, heat, autoclave, or any other harsh method to sterilize this thermometer.

Caution: The Genius 3 Tympanic Thermometer and Base are not designed to be immersed, soaked, rinsed, or sprayed with water. Do not immerse, soak, rinse, or spray the Genius 3 Tympanic Thermometer or Base in water or other cleaning solutions. Failure to follow the cleaning procedures described herein could result in hazards to users, patients, and clinicians. As with any medical electrical equipment, care must be taken to prevent liquid from entering the thermometer to avoid electrical shock hazard, fire hazard, or damage to the electrical components.

Caution: If leakage into the thermometer interior occurs, **do not use** the thermometer until it has been properly cleaned, dried, and checked for accuracy. Accuracy can be verified with the Genius Checker/Calibrator. For assistance please contact Customer Service.

Section VII — Battery Replacement

The batteries (3 AAA) should be changed when the low battery icon appears on the display. After the low battery icon is shown, about 100 readings can be taken before the dead battery display will appear. Once the dead battery display is shown, no more readings can be taken.

To change the batteries, remove the cover on the bottom of the unit. Note the polarity of the installed batteries. Remove the old batteries and replace with new, using the correct polarity. Replace the battery cover and secure it with the screws.

Section VIII — Mounting Instructions

A wall mount or cart mount (sold separately) are available for the base unit. Follow the instructions supplied with those items.

Section IX — Troubleshooting

If the thermometer is not working properly, check the following:

Symptom	Action
Temperature reading unusually high	Check the probe cover for tears or gaps.
Temperature reading unusually low	Check the probe cover and thermometer tip for debris. Check the patient ear canal for debris.
Low battery indicator lit	Replace the batteries.
Dead battery indicator lit	Replace the batteries.
Display blank	Replace the batteries.
System error displayed	If System Error "1" and System Error "2" is shown, allow the device to stabilize for 20 minutes before use. For all other system errors the thermometer can be reset by installing a probe cover. If the system error does not clear, send the thermometer for service. The service information is located in Section XI, Customer Service.

The Genius 3 Tympanic Thermometer and Base advisories and alarms are described in the Thermometer Display Icons and Alarms section of Section IV, Instructions for Use.

Section X — Specifications

Clinical accuracy characteristics and procedures are available from the manufacturer on request. To verify accuracy, use a certified blackbody as specified in ISO 80601-2-56 or use a Genius Checker/Calibrator – order part number 303097.

Calibrated Accuracy Limits:

Ambient Temperature	Target Temperature	Accuracy
16°C to 33°C (60.8°F to 91.4°F)	33°C to 42°C (91.4°F to 107.6°F)	± 0.3°C (± 0.5°F)

Calibrated Accuracy Limits (after Recalibration*):

Ambient Temperature	Target Temperature	Accuracy
16°C to 33°C (60.8°F to 91.4°F)	33°C to 42°C (91.4°F to 107.6°F)	± 0.3°C (± 0.5°F)

*Post recalibration accuracy using the Genius Checker/Calibrator may not necessarily be equivalent to factory calibration.

Displayed Temperature Measurement Range:

Temperature Range depends on Site Mode as follows:

Mode	Range °C	Range °F
Ear	33.0 to 42.0	91.4 to 107.6
Oral	33.0 to 41.9	91.4 to 107.4
Rectal	33.6 to 42.0	92.4 to 107.6

Ambient Temperature Range:

16°C to 33°C (60.8°F to 91.4°F), 15% to 90% RH, non condensing.

Transport and Storage Temperature Range:

-25°C to 55°C (-13°F to 131°F), up to 90% RH non-condensing. If the unit is stored at extremes, it is recommended that the unit be checked on the field calibration checker or at the factory before returning to service.

Ambient Air Pressure

Operating atmospheric pressure range from 70kPA to 106kPA

Clinical Repeatability:

Clinical repeatability in compliance to ISO 80601-2-56 already published under Equivalence Mode in Section IV, Instructions for Use.

Response Time: 1 - 2 seconds

Pulse Timer:

60 seconds

Temperature Resolution:

0.1°C or 0.1°F

Power:

Internally Powered ME Equipment
3 AAA alkaline batteries

Battery Life:

Minimum of 15,000 temperature readings

Size:

Thermometer — 17.8 cm (7″)
Base — 20.3 cm (8″)

Weight:

Thermometer (with batteries) — 160 grams
Base — 100 grams

Degree of Protection Against Electrical Shock:

Type BF

Mode of Operation:

Non- Continuous ADJUSTED MODE

Degree of Protection Against Ingress of Fluids:

Drip Proof – IP22

Expected Service Life:

3 Years

Device and Safety Standards:

The Genius 3 Tympanic Thermometer and Base meets:

• ISO 80601-2-56:2017 • IEC 60601-1:2005/AMD1:2012 • IEC 60601-1-2:2014

The device meets ISO 80601-2-56:2017 subject to the following conditions:

1. The precision of the measurements taken during testing was increased from one significant digit to four significant digits.
2. The increased precision numbers were then averaged to account for the known variance in measurements taken due to human factors.

Contact your Covidien Representative for questions regarding standards compliance and national differences.

Section XI— Customer Service

In the event that it is necessary to return a unit for repair, please observe the following:

1. Contact Covidien technical service as shown below for the correct return procedure.
2. Ship insured parcel to your local service contact or the appropriate location below.

United States	Europe	All Others
Covidien 2824 Airwest Blvd. Plainfield, IN 46168 USA 1-800-448-0190	Covidien EMEA Customer Care & Supply Chain Solution Management & Operational Excellence Earl Bakkenstraat 10, Heerlen, 6422 PJ The Netherlands	Contact Covidien Sales Representative

Parts Listing

To order repair parts, please contact your local customer service center or sales representative for the parts listed below.

Description	Order Part Number
Genius 3 Thermometer with Base	303013
Genius Probe Cover	303030
Genius Checker/ Calibrator	303097
Genius 3 Replacement Base	PT00057207
Genius 3 Replacement Coil Cord	PT00073918
Genius 3 Replacement Battery Door	PT00047836
Genius 3 Locking Mount for Wall	303058
Genius 3 Cart with Locking Mount	303059

Section XII— Warranty

Limited Warranty: Covidien warrants to the original purchaser ("Customer") that this product will be free of defects in materials and workmanship, under normal use, for three (3) years from the date of original purchase from Covidien or its authorized distributor. If this product does not operate as warranted above during the applicable warranty period, Covidien may, at its option and expense, replace the defective part or product, or, if neither replacement nor repair is reasonably available, refund to Customer the purchase price for the defective part or product. Dated proof of original purchase will be required.

Covidien does not assume any liability for loss arising from unauthorized repair, misuse, neglect, chemical damage or accident. Removal, defacement, or alteration of serial lot number voids warranty. Covidien disclaims all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose or application other than expressly set forth in the product labeling.

Except as otherwise required or prohibited under local law, the warranty set forth in this section is the sole and exclusive warranty as to the products, and is expressly in lieu of any other warranty, oral or implied, including without limitation any oral or implied warranty of merchantability or fitness for a particular purpose. Except as otherwise required or prohibited under local law, Covidien shall not be liable for any incidental, special or consequential loss, damage, or expense (including, without limitation, lost profits) directly or indirectly arising from the sale, inability to sell, use or loss of use of any product.

Section XIII – Electromagnetic Conformity Declaration

The Genius 3 Tympanic Thermometer and Base has been built and tested according to IEC60601-1, CAN/CSA C22.2 No. 60601-1:14, and EN60601-1-2 Standards.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Genius 3 Tympanic Thermometer and Base is intended for use in the electromagnetic environment specified below. The user of the Genius 3 Tympanic Thermometer and Base should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions (CISPR 11)	Group 1	The Genius 3 Tympanic Thermometer and Base uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class B	The Genius 3 Tympanic Thermometer and Base is suitable for use in the Professional healthcare and Home healthcare environments.
Harmonic emissions (IEC 61000-3-2)	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Genius 3 Tympanic Thermometer and Base is intended for use in the electromagnetic environment specified below. The user of the Genius 3 Tympanic Thermometer and Base should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) (IEC 61000-4-2 per EN 60601-1-2:2015	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 1 kV	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % UT 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT 1 cycle and 70 % UT for 25/30 cycles single phase: at 0°	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycles	not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field (EN 61000-4-8 per EN 60601-1-2: 2015)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Genius 3 Tympanic Thermometer and Base is intended for use in the electromagnetic environment specified below. The customer or the user of the Genius 3 Tympanic Thermometer and Base should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Radiated RF (EN 61000-4-3 per EN 60601-1-2: 2015)	10 V/m 80MHz to 200MHz 10 V/m 200MHZ to 325MHz 10 V/m 325MHz to 370MHz 10 V/m 370MHz to 700MHz 10 V/m 700MHz to 1000MHz 10 V/m 1000MHz to 1335MHz 10 V/m 1335MHz to 1800MHz 10 V/m 1800 MHz to 2700MHz	10 V/m 3V/m 10 V/m 3 V/m 10 V/m 3 V/m 10 V/m 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Genius 3 Tympanic Thermometer and Base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Genius 3 Tympanic Thermometer and Base is used exceeds the applicable RF compliance level above, the Genius 3 Tympanic Thermometer and Base should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Genius 3 Tympanic Thermometer and Base.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Genius 3 Tympanic Thermometer and Base

The Genius 3 Tympanic Thermometer and Base is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Genius 3 Tympanic Thermometer and Base can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Genius 3 Tympanic Thermometer and Base recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Minimum separation distances between the Genius 3 and proximity fields from RF wireless communications equipment found in the Professional healthcare facility environment

New digital wireless technologies have been introduced in healthcare and various locations where medical electrical equipment and systems are used. RF wireless communications equipment should be used no closer than the minimum separation distance stated below when taking temperature readings with the Genius 3 thermometer.

Service	Frequency MHz	Maximum Power of Transmitter W	Minimum Separation Distance* m
2-way	385	1.8	**
2-way; walkie-talkie	450	2	**
cellular	710	0.2	0.3
cellular	745	0.2	0.3
cellular	780	0.2	0.3
cellular	810	2	0.3
cellular	870	2	0.3
cellular	930	2	0.3
cellular	1720	2	0.3
cellular	1845	2	0.6
cellular	1970	2	0.45
Wi Fi; Bluetooth; RFID; cellular	2450	2	0.57
Wi Fi	5240	0.2	0.54
Wi Fi	5500	0.2	0.54
Wi Fi	5785	0.2	0.67

*Values for minimum separation distance based on actual test data. Frequency and Maximum Power values were obtained from Table 9 of IEC 60601-1-2:2014. The Genius 3 will maintain laboratory accuracy in its rated output range in accordance with ISO 80601-2-56:2017 when the minimum separation distance is met.

** The Genius 3 thermometer is not intended to be used in close proximity to 2-way radios and walkie-talkie radios commonly used by personnel operating in emergency vehicles such as ambulances and helicopters. Using the Genius 3 near this type of communication equipment can cause erroneous temperature readings.

Warning: Portable or mobile wireless RF communications equipment should be used no closer to the Genius 3 thermometer than stated above. Otherwise, degradation of the performance of the Genius 3 could result.

If the Genius 3 thermometer is to be used near transmitters having maximum power other than the values listed in the table, the separation distance can be calculated with the following equations:

For transmitters operating at frequencies within range 704 to 787 MHz: $d = \frac{6}{9}\sqrt{P}$

For transmitters operating at frequencies within range 800 to 2570 MHz: $d = \frac{6}{28}\sqrt{P}$

For transmitters operating at frequencies within range 5100 to 5800 MHz: $d = \frac{6}{9}\sqrt{P}$

where d is the distance in meters and P is the transmitter power in Watts.

NON STERILE

Rx ONLY

Follow instructions for use. Symbol appears blue on device.

CE 0123

COVIDIEN

Manual No. HP112001

Made in China.

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

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